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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/790,182	03/02/2004	Saul Yedgar	P-2507-US2	3956

27130 7590 01/13/2006

EITAN, PEARL, LATZER & COHEN ZEDEK LLP
10 ROCKEFELLER PLAZA, SUITE 1001
NEW YORK, NY 10020

EXAMINER	
O SULLIVAN, PETER G	

ART UNIT	PAPER NUMBER
1621	

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding

ATTORNEY: RTB

ACTION: D-OA DUE: 13 Apr 06

ACTION: _____ DUE: _____

ACTION: _____ DUE: _____

DOCKETED BY: JP DATE: 23/1/06

Office Action Summary

Application No.	Applicant(s)	
10/790,182	YEDGAR ET AL	
Examiner	**Art Unit**	
Peter G. O'Sullivan	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-21 are pending in this application which should be reviewed for errors. In response to the requirement for the election of a single disclosed species, applicants elected phosphatidylethanolamine bound to glycosaminoglycans. All other compounds and methods are held withdrawn from consideration.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention

Claims 8-14 provides for the use of applicants' compounds, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 8-14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

Claims 15-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoki et al., US 5,470,578, who disclose anticipating chondroitin and hyaluronic acid derivatives in the examples.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teaching of Yedgar et al., US 5,064,817, Chaikof et al., US 6,171,614, and Aoki et al., US 5,470,578, in view of Pruzanski et al.,US 6,043,231, Sorgente et al., US 6,162,787, and Falk et al., US 6,022,866. Yedgar et al. disclose anti-inflammatory derivatives including distearoyl phosphatidylethanolamines covalently bonded through the amine group to carrier moieties which may include polysaccharides (s. Col. 2, ll. 50-58 and Col. 4, ll. 43-59). Yedgar et al. disclose their compounds to be PLA2 inhibitors,

thus having utility in a wide variety of oversecretory disease states such as allergic response, inflammation, atherosclerosis, thrombosis, etc. (Col. 13, top and middle). Although chondroitin and hyaluronic acid are not specifically mentioned by Yedgar et al. as carrier moieties, their listing is clearly not meant to be exhaustive. Chondroitin sulfate and hyaluronic acid are polysaccharides. Chaikof et al. disclose targeting of therapeutic agents using glycophospholipids generically overlapping applicants' (s. Col. 3, bottom). Chaikof et al. disclose the saccharide derivative used in the glycophospholipid may itself be therapeutic and specifically mentions chondroitin sulfate (s. Col. 5, second and third paragraphs). Aoiki et al., disclose antirheumatic compositions generically overlapping applicants' with anticipating examples (s. examples).

The instant invention differs from the teaching of the cited references in that applicants' activity against intestinal diseases is not specifically disclosed and in that other compounds are claimed which are not specifically exemplified. Pruzanski et al. is relied on to teach PLA2 inhibiting compounds to be useful in treating inflammatory bowel diseases and various inflammatory disorders. Sorgente et al. disclose chondroitin sulfate to be useful as an anti-inflammatory. Falk et al. is relied on to teach hyaluronic acid itself to be useful in the atherosclerotic process of restinosis. Especially in view of the teaching of Chaikof et al. that the saccharide derivative itself may be therapeutic, it would have been prima facie obvious at the time the invention was made to start with the teaching of the cited references, to make applicants' compounds and to expect to produce compound and compositions useful as anti-inflammatory agents or

agents in the treatment of disease states such as atherosclerosis, inflammatory bowel diseases, etc. To make further compounds generically disclosed, but not specifically exemplified would be further prima facie obvious in view of close or anticipating compounds already made.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/756,765. Although the conflicting claims are not identical, they are not patentably distinct from each other because applicants' compositions would be obvious over their compounds. P-3507-US

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication should be directed to Peter G. O'Sullivan at telephone number (571)272-0642.

PETER O'SULLIVAN
PRIMARY EXAMINER

Please type a plus sign (+) inside this box → +

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	10/790,182
Filing Date	March 2, 2004
First Named Inventor	YEDGAR, Saul
Group Art Unit	1621
Examiner Name	O'Sullivan, Peter G
Attorney Docket Number	P-2507-US2

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
PO	A	5,470,578		Aoki et al.	Nov 28, 1995	
	B	6,071,532		Chaikof et al.	Jun 6, 2000	
	C	6,171,614		Chaikof et al.	Jan 9, 2001	
	D	6,022,866		Falk et al.	Feb 8, 2000	
	E	6,043,231		Pruzanski et al.	Mar 28, 2000	
	F	5,464,942		Sakurai et al.	Nov 7, 1995	
	G	6,162,787		Sorgente et al.	Dec 19, 2000	
PO	H	5,064,817		Yedgar et al.	Nov 12, 1991	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[6]
PO	I	WO	98016198		Chaikof et al.	Apr 23, 1998		☐
	J	WO	9628544		Flodgaard, et al.	Sep 19, 1996		☐
	K	WO	9701330		Parikh	Jan 16, 1997		☐
	L	EP	0581282B		Seikagaku, et al.	Feb 2, 1994		☐
PO	M	JP	09030979		Sugiura et al.	Feb 4, 1997		☒

Examiner Signature		Date Considered	Jun 2006

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[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/790,182
				Filing Date	March 2, 2004
				First Named Inventor	YEDGAR, Saul
				Group Art Unit	1621
(use as many sheets as necessary)				Examiner Name	O'Sullivan, Peter G
Sheet	2	of	3	Attorney Docket Number	P-2507-US2

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
/PO/	N	ALBINI, A. IWAMOTO, Y. KLEINMAN, HK. MARTIN, GR. AARONSON, SA. KOZLOWSKI, JM AND MCEWAN, RN (1987) "A rapid in vitro assay for quantitating the invasive potential of tumor cells" Cancer Res 47(12):3239-45	☐
	O	BALSINDE, J, BALBOA, MA, YEDGAR, S AND DENNIS, EA (2000) "Group V phospholipase A(2)-mediated oleic acid mobilization in lipopolysaccharide-stimulated P388D(1) macrophages" J Biol Chem 275(7):4783-6	☐
	P	BECK, G, YARD, BA, SCHULTE, J, OBERACKER, R, VAN ACKERN, K, VAN DER WOUDE, FJ, KRIMSKY, M, KASZKIN, M AND YEDGAR, S (2002) "Inhibition of LPS-induced chemokine production in human lung endothelial cells by lipid conjugates anchored to the membrane" Br J Pharmacol 135(7):1665-74	☐
	Q	CABANAS, C AND HOGG, N (1993) "Ligand intercellular adhesion molecule 1 has a necessary role in activation of integrin lymphocyte function-associated molecule 1" Proc Natl Acad Sci U S A 90(12):5838-42	☐
	R	CHEN, WM, SORIA, J, SORIA, C, KRIMSKY, M AND YEDGAR, S (2002) "Control of capillary formation by membrane-anchored extracellular inhibitor of phospholipase A(2)" FEBS Lett 522(1-3):113-8	☐
	S	DAN, P, DAGAN, A, KRIMSKY, M, PRUZANSKI, W, VADAS, P AND YEDGAR, S (1998) "Inhibition of type I and type II phospholipase A2 by phosphatidyl-ethanolamine linked to polymeric carriers" Biochemistry 37(17):6199-204	☐
	T	GREAVES, MW AND CAMP, RD (1988) "Prostaglandins, leukotrienes, phospholipase, platelet activating factor, and cytokines: an integrated approach to inflammation of human skin" Arch Dermatol Res 280:S33-41	
	U	KRIMSKY, M, DAGAN, A, APTEKAR, L, LIGUMSKY, M AND YEDGAR, S (2000) "Assessment of intestinal permeability in rats by permeation of inulin-fluorescein" J Basic Clin Physiol Pharmacol 11(2):143-53	☐
	V	KRIMSKY, M, YEDGAR, S, APTEKAR, L, SCHWOB, O, GOSHEN, G, GRUZMAN, A, SASSON, S AND LIGUMSKY, M (2003) "Amelioration of TNBS-induced colon inflammation in rats by phospholipase A2 inhibitor" Am J Physiol Gastrointest Liver Physiol 285(3):G586-92	☐
	W	MARGOLIS-NUNNO, H, BEN-HUR, E, GOTTLIEB, P, ROBINSON, R, OETJEN, J AND HOROWITZ, B (1996) "Inactivation by phthalocyanine photosensitization of multiple forms of human immunodeficiency virus in red cell concentrates" Transfusion 36(8):743-50	☐
	X	MURTHY, SN, COOPER, HS, SHIM, H, SHAH, RS, IBRAHIM, SA AND SEDERGRAN, DJ (1993) "Treatment of dextran sulfate sodium-induced murine colitis by intracolonic cyclosporin" Dig Dis Sci 38(9):1722-34	☐
/PO/	Y	OKAYASU, I, HATAKEYAMA, S, YAMADA, M, OHKUSA, T, INAGAKI, Y AND NAKAYA, R (1990) "A novel method in the induction of reliable experimental acute and chronic ulcerative colitis in mice" Gastroenterology 98(3):694-702	☐

Examiner Signature	/P.O'S/	Date Considered	Jan 2006

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/790,182
				Filing Date	March 2, 2004
				First Named Inventor	YEDGAR, Saul
				Group Art Unit	1621
(use as many sheets as necessary)				Examiner Name	O'Sullivan, Peter G
Sheet	3	of	3	Attorney Docket Number	P-2507-US2

Examiner Signature		Date Considered	

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T [2]
	Z	SCHMIEL, DH AND MILLER, VL (1999) "Bacterial phospholipases and pathogenesis" Microbes Infect 1(13):1103-12	☐
	AA	SCHNITZER, E, DAGAN, A, KRIMSKY, M, LICHTENBERG, D, PINCHUK, I, SHINAR, H AND YEDGAR, S (2000) "Interaction of hyaluronic acid-linked phosphatidylethanolamine (HyPE) with LDL and its effect on the susceptibility of LDL lipids to oxidation" Chem Phys Lipids 104(2):149-60	☐
	BB	SCHNITZER, E, PINCHUK, I, FAINARU, M, LICHTENBERG, D AND YEDGAR, S (1998) "LDL-associated phospholipase A does not protect LDL against lipid peroxidation in vitro" Free Radic Biol Med 24(7-8):1294-303	☐
	CC	SCHNITZER, E, YEDGAR, S, DANINO, D, TALMON, Y AND LICHTENBERG, D (1999) "The interaction of hyaluronic-phosphatidylethanolamine with low density lipoprotein (LDL) and its effect on copper induced LDL oxidation" Biophysical Journal 76(1): Part 2	☐
	DD	YARD, BA, YEDGAR, S, SCHEELE, M, VAN DER WOUDE, D, BECK, G, HEIDRICH, B, KRIMSKY, M, VAN DER WOUDE, FJ AND POST, S (2002) "Modulation of IFN-gamma-induced immunogenicity by phosphatidylethanolamine-linked hyaluronic acid" Transplantation 73(6):984-92	☐
	EE	YEDGAR, S, LICHTENBERG, D AND SCHNITZER, E (2000) "Inhibition of phospholipase A(2) as a therapeutic target" Biochim Biophys Acta 1488(1-2):182-7	☐
			☐
			☐

2006

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 2

Complete if Known	
Application Number	91397
Filing Date	August 23, 1989
First Named Inventor	
Group Art Unit	
Examiner Name	
Attorney Docket Number	P-57917-IL

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
IA*	A	5,084,817		YEDGAR Shaul et al.	Nov 12, 1991	
IAD	B	6,171,614		CHAIKOF Elliot L. et al.	Jan 9, 2001	
IA1	C	6,162,787		SORGENTE Nino	Dec 19, 2000	

FOREIGN PATENT DOCUMENTS

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	D	Group V Phospholipase A_2-mediated Oletic Acid Mobilization in Lipopolysaccharide-stimulated P388D$_1$ Macrophages; BALSINDE Jesus, BALBOA Maria A., YEDGAR Saul, and DENNIS Edward A., The Journal of Biological Chemistry, Vol 275, Feb 18 pp4783-4786	☐
	E	Inhibition of LPS-induced chemokine production in human lund endothelial cells by lipid conjugates achored to the membrane BECK, G. Ch, YARD B.A. SCHULTE J., OBERACKER. R, VAN ACKERN K, VAN DER WOUDE F.J, KRIMSKY M, KASZKIN M and YEDGAR Y.; British Journal of Pharmacology (2002) 135, 1665-1674	☐
	F	Control of capillary formation by membrane-anchored extracellular inhibitor of phospholipase A_2; CHEM, W.M, SORIA J, CORIA C, KRIMSKY M and YEDGAR S.; FEBS 26215 letters 522 (2002) 113-118	☐
	G	Interaction of hyaluronic acid-linked phophatidylethonolmine (HyPE) with LDL and its effect on the susceptibility of LDL lips to oxidation; SCHNITZER Edit, DAGAN Arie, KRIMSKY Miron, LICHTENBERG Dov, PINCHUK Ilya, SHINAR Hadassa, YEDGAR Saul; CPL 104 (2000) 149-160	☐
	H	Inhibition of phopholipase A2 as a therapeutic target; YEDGAR Saul, LICHTENBERG Dov, SCHNITZER Edit, BBA Biochimica et Biophyscia Acta 1488 (2000) 182-187	☐
	I	Modulation of IFN-GAMMA-induced immunogenicity by phosphatidylethanolamine-linked hyaluronic acid; YARD Benito A., YEDGAR Saul, SCHEELE Martin, VAN DER WOULDE Diane, BECK Grietje, HEIDRICH Barbel, KRIMSKY Miron,. VAN DER WOULDE Fokko J, and POST Stefan TRANSPLANTATION Vol 73, 984-992, No. 6, March 27, 2002	☐
	J	Inhibition of Type I and Type II Phospholipase A_2 by Phosphatidyl-Ethanloamine Linked to Polymeric Carriers; PHYLLIS Dan, ARIE Dagan, MIRON Krimsky, WALDEMAR Pruzanski, PETER Vadas, and Saul Yedgar. Biochemistry 1998, 37, 6199-6204	☐

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